Decision Memo for Home Use of Oxygen (CAG-00296N)

Decision Summary

The Centers for Medicare & Medicaid Services (CMS) will cover the home use of oxygen as detailed in Section 240.2 of the CMS National Coverage Determinations Manual for beneficiaries who have arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% when they are enrolled in clinical trials approved by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI). The list of identified trials that are covered will be listed on the following CMS website: http://www.cms.hhs.gov/coverage.

This decision does not modify the existing requirement for coverage of oxygen currently identified in Section 240.2.

As a condition of coverage, investigators must adhere to the provisions of Health Insurance Portability and Accountability Act (HIPAA), the Privacy Act, Paperwork Reduction Act (PRA), and 45 CFR Part 46, if applicable.

We are adding the following text to Section 240.2.D.3(c) of the National Coverage Determinations Manual:

The home use of oxygen is covered for those beneficiaries with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI).

Back to Top

Decision Memo

TO: Administrative File: CAG #00296
Home Use of Oxygen

FROM:

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group

Louis Jacques, MD
Division Director

Karen Daily, MS
Lead Analyst

Tiffany Sanders, MD
Lead Medical Officer

Leslye Fitterman, PhD
Epidemiologist

SUBJECT: Decision Memorandum for Home Use of Oxygen
DATE: March 20, 2006

I. Decision

The Centers for Medicare & Medicaid Services (CMS) will cover the home use of oxygen as detailed in Section 240.2 of the CMS National Coverage Determinations Manual for beneficiaries who have arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% when they are enrolled in clinical trials approved by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI). The list of identified trials that are covered will be listed on the following CMS website: http://www.cms.hhs.gov/coverage.

This decision does not modify the existing requirement for coverage of oxygen currently identified in Section 240.2.

As a condition of coverage, investigators must adhere to the provisions of Health Insurance Portability and Accountability Act (HIPAA), the Privacy Act, Paperwork Reduction Act (PRA), and 45 CFR Part 46, if applicable.

We are adding the following text to Section 240.2.D.3(c) of the National Coverage Determinations Manual:

The home use of oxygen is covered for those beneficiaries with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI).

II. Background

Oxygen is a naturally occurring element present in the atmosphere at a sea level concentration of approximately 21% in a gaseous state. Oxygen is readily available to the general public from commercial sources, and has a variety of therapeutic, industrial and other uses. Medical research has amply demonstrated that administration of oxygen in higher concentrations than normal atmospheric concentration has beneficial effects in the treatment of certain persons who have some disease conditions, and thus, oxygen therapy is no longer considered experimental. In fact, CMS paid for oxygen for approximately 850,000 Medicare beneficiaries in 2004 and estimates project that 1,100,000 beneficiaries will receive oxygen in 2007.

Therapeutic administration of supplemental oxygen is generally classified as acute (to meet a short term need) or chronic (for long term use). Chronic oxygen administration is most closely related to the treatment of persons with chronic obstructive pulmonary disease (COPD) and other chronic medical conditions. These conditions typically manifest over a continuum from mild to serious to life-threatening severity.

Epidemiology

COPD is the most common chronic lung disease in the United States and the hypoxemia associated with severe COPD is the most common indication for the use of long-term supplemental oxygen. Less common indications for long term supplemental oxygen therapy may include hypoxemia accompanying severe stages of other pulmonary conditions and severe stages of certain chronic cardiac conditions such as recurring congestive heart failure due to cor pulmonale. However, many pulmonary and cardiac conditions are not appropriate for treatment with long term supplemental oxygen. We discuss COPD in more detail to provide the general public with additional background information about this common condition. An exhaustive review of all possible causes of hypoxemia amenable to long term supplemental oxygen therapy is beyond the scope of this decision memorandum.

COPD is a progressive disorder of the airways that is characterized by a gradual loss of lung function and airflow limitation that is not fully reversible. The symptoms of COPD can range from chronic cough and sputum production to severe shortness of breath. In the U.S., the most important risk factor for the development of COPD is cigarette smoking. COPD is the fourth ranking cause of death in the U.S. and approximately 100,000 people per year die because of the condition.[1] Approximately 12 million adults are diagnosed with the disorder each year.

Persons with COPD also suffer considerable morbidity related to their disease process, including: frequent physician visits or hospitalizations for symptom management, and decline in quality of life secondary to significant difficulty breathing and loss of functional ability.

Disease Process

One of the hallmarks of COPD is the noted abnormalities in the exchange of oxygen and carbon dioxide in the lungs. As a result, patients with COPD suffer from hypoxemia, a condition in which there is inadequate supply of oxygen to blood and tissues. In advanced stages of COPD, hypoxemia worsens to the point where patients require the use of supplemental oxygen therapy to maintain survival.

Interaction of the Intervention with the Disease Process

Criteria have been developed in an attempt to identify those COPD patients who are most likely to benefit from supplemental/long-term oxygen therapy by prolonging survival and preventing further disease related complications such as end organ damage and further reduction in quality of life. It is generally recognized by the medical community that COPD patients with an arterial oxygen partial pressure measurement (PaO_2) $\leq$ 55 mmHg or those with PaO_2 measurements between 56-59 mmHg with evidence of end organ disease (pulmonary hypertension, cor pulmonale, polycythemia, arrhythmias, congestive heart failure, or impaired mental status) benefit from the use of long term oxygen therapy (LTOT).[2,3] These criteria are based largely on two randomized controlled trials performed in 1980 and 1981. However, there is less scientific evidence evaluating the net health outcomes for the subgroup of COPD patients with PaO_2 measurements between 56-65 mmHg receiving LTOT as a therapeutic modality.

The use of supplemental oxygen is not without risk. Although generally perceived by the public at large as beneficial with few if any consequences other than enhanced risk of fire, adverse events and potential toxicity related to oxygen have been described in the medical literature. Prudent medical practitioners consider this when they assess patients for possible therapy with supplemental oxygen, weighing the relevant risks and benefits as they formulate their treatment recommendations. In various populations the reported risks include suppression of respiration, systemic oxidative stress, pulmonary damage, cataracts, vasoconstriction and ischemia, drying of the mucosal surfaces of the respiratory tract with resultant inflammation, cognitive decline, acidosis, and others.

III. History of Medicare Coverage

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. § 1812 (Scope of Part A); § 1832 (Scope of Part B) § 1861(s) (Definition of Medical and Other Health Services). Provided that all coverage requirements are met, Medicare covers home use of oxygen as a supply to durable medical equipment (DME), which is referenced in section 1861(s)(6) of the Social Security Act. Equipment associated with delivering oxygen such as oxygen concentrators, portable, and stationary oxygen systems qualify as DME, while the oxygen contents serve as the DME supply. Thus, the home use of oxygen falls within the DME benefit category.

Medicare has a National Coverage Determination on Home Use of Oxygen (Rev. 1, 10-03-03) at Section 240.2 of the National Coverage Determinations Manual. In that NCD, CMS covers home oxygen for beneficiaries with severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or with hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy to include pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache. In addition to these conditions, beneficiaries must have lab values that fit into one of three groups:

Group I - Patients with significant hypoxemia evidenced by any of the following:

- A PaO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken at rest, breathing room air.
- A PaO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a patient who demonstrates a PaO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in PaO_2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5 percent) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia).
- A PaO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a patient who demonstrates a PaO_2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

Group II - Patients whose PaO_2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89 percent, if there is evidence of:

- Dependent edema suggesting congestive heart failure;
- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); or
- Erythrocythemia with a hematocrit greater than 56 percent.

Group III – Contractors have discretion to cover home oxygen for patients with PaO_2 levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90 percent if appropriate medical documentation is submitted.

In reviewing the PaO_2 levels and the arterial oxygen saturation percentages, the carrier's medical staff must take into account variations in oxygen measurements that may result from such factors as the patient's age, the altitude level, or the patient's decreased oxygen carrying capacity.

Medicare also covers the routine clinical costs for Medicare beneficiaries enrolled in clinical trials that meet the criteria of the Clinical Trial Policy (Section 310.1 of the National Coverage Determination Manual).

IV. Timeline of Recent Activities

August 16, 2005

	CMS opened an internally generated National Coverage Determination (NCD) reconsideration to determine if there is sufficient evidence to change the current policy for beneficiaries having arterial oxygen partial pressure measurements in the range 56-65 mmHg.
	The initial 30-day public comment period began.
September 16, 2005	End of public comment period.
December 20, 2005	Proposed decision memorandum posted with a 30 day public comment period

V. FDA Status

Oxygen itself is a naturally occurring element, readily available commercially from a variety of industrial and other sources. While the FDA regulates the equipment and delivery systems required for providing oxygen therapy, it does not regulate the use of oxygen.

VI. General Methodological Principles

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for patients. An improved net health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comment sometimes cites to published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore are not usually as persuasive as other types of evidence considered in making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

We are providing a summary of the evidence we considered during our review. The evidence reviewed to date in this NCD includes the published medical literature on pertinent clinical trials of home oxygen.

B. Discussion of evidence reviewed

1. Question

Is the quality of evidence adequate to conclude that the home use of oxygen can improve net health outcomes and is reasonable and necessary for Medicare beneficiaries who have arterial oxygen partial pressure measurements from 56 mmHg to 65 mmHg or whose oxygen saturation is at or above 89%?

2. External technology assessments

In 2004, CMS requested an external technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ) in order to summarize the available clinical and scientific evidence on the appropriateness and effective use of LTOT in patients with COPD.[4] The TA authors concluded that there is insufficient scientific evidence to assess the survival benefit of patients with COPD and PaO_2 measurements in the range of 56-65 mmHg. This conclusion is based on the lack of scientifically rigorous evidence used to guide the use of LTOT in COPD patients. In addition, the majority of studies reviewed by the TA authors reported findings for the subgroup of patients with severe resting hypoxemia or moderate hypoxemia with certain advanced manifestations of disease such as concomitant cardiac impairment. Inconsistencies in identifying or reporting evidence regarding non-mortality outcomes such as rates of hospitalization, improvement in lung physiology, and quality of life measures were also noted by the TA authorities. This information was subsequently presented as part of an expert working group convened by NHLBI to discuss LTOT in May of 2004.[5] The NHLBI report cited the efficacy of LTOT in patients with moderate resting hypoxemia as an important future research initiative. Hours of oxygen utilization, therapeutic benefits independent of survival, and the identification of specific population subgroups such as those with pulmonary hypertension or low BMI were identified as important to informing the current body of evidence regarding COPD patients and LTOT as a therapeutic modality.

3. Internal technology assessments

Systematic reviews are based on a comprehensive search of published studies to answer a clearly defined and specific set of clinical questions. A well-defined strategy or protocol (established before the results of the individual studies are known) guides this literature search. Thus, the process of identifying studies for potential inclusion and sources for finding such articles is explicitly documented at the start of the review. Finally, systematic reviews provide a detailed assessment of the studies included.

Literature search methods

A search of the MEDLINE database, The Cochrane Library, the National Guidelines Clearinghouse, and the International Network of Agencies for Health Technologies Assessment (INAHTA) database and a hand search of bibliographies included in the articles were conducted. The internal TA searched for and evaluated literature addressing the subgroup of patients with COPD with PaO_2 measurements in the range of 56-65 mmHg receiving LTOT as the major treatment modality. Filters and limitations were used, and inclusion and exclusion criteria were developed to identify the appropriate articles to be reviewed.

Evidence Review

Compared to hypoxemic patients with arterial PaO_2 measurements at or below 55mmHg, there is a smaller volume of published scientific evidence available to evaluate the net health outcomes of long term oxygen therapy for hypoxemic patients with arterial PaO_2 measurements in the range of 56-65mmHg.

Sliwiński (1992) performed a prospective cohort study of 46 patients with COPD in order to determine the acute effect of oxygen on pulmonary artery pressure (PAP). Participants were divided into two groups, those with $PaO_2 \leq 55$ mmHg or PaO_2 56-65 mmHg if accompanied by radiologic signs of pulmonary hypertension, ECG signs of right ventricular hypertrophy, or elevated hematocrit. They were further classified as responders and non-responders based on changes in PAP in relation to treatment with oxygen. The number or percentage of patients in each group was not reported and results were not categorized by group. The average use of oxygen was reported as 14.6h/day. Outcome measures of interest included survival and hospitalizations related to COPD exacerbations. The two year survival rate was 69% in non-responders and 57% in responders. On average there were 1.4 versus 0.8 hospital admissions when comparing non-responders and responders.

Sandek (2001) performed a prospective cohort study of 14 patients with COPD and PaO_2 measurements in the range of 56-59 mmHg to determine the effect of LTOT on pulmonary function and other physiological measurements. No significant changes were noted. The author concluded that six months of LTOT in stable COPD patients does not correlate to clinically important changes in pulmonary physiology.

Gorecka (1997) performed a randomized clinical trial of 135 COPD patients with PaO_2 measurements in the range of 56-65 mmHg. Patients were randomized to conventional therapy with or without LTOT. Outcome measures of interest included survival, hours of oxygen use, and survival predictors. There was no significant difference in survival in the control and treatment arms of the trial. In addition, oxygen use greater than 15 hours per day did not improve survival. Younger age, spirometric values, and higher BMI were predictors of survival. The cumulative survival rates at one, two, and three years were 88%, 77%, and 66%.

Hjalmarsen (1999) completed a retrospective study of 124 patients with COPD. Patients were divided into two groups based on PaO_2 measurements: Group I $PaO_2 \leq 55$ mmHg and Group II $PaO_2 \geq 56$ mmHg with coexisting polycythemia or cor pulmonale. The major outcome of interest was survival. The authors concluded that survival was similar for both patient groups at the same level of loss of lung function.

An additional randomized control trial study by Chaouat (1999) evaluated COPD patients with PaO_2 measurements in the range of 60-64 mmHg. However, patients only received oxygen therapy at night. Authors noted no significant difference in mortality between the treated and control groups based on an intention to treat analysis.

4. MCAC

A Medicare Coverage Advisory Committee (MCAC) meeting was not convened on this issue.

5. Evidence-based guidelines

Institute for Clinical Systems Improvement (ICSI). Chronic obstructive pulmonary disease. Bloomington (MN): 2004 Dec.

The guidelines note that LTOT improves survival and quality of life in hypoxemic patients and should be used as supplemental therapy for patients with resting $PaO_2 \leq 55$ mmHg. No specific guidance was given for patients with PaO_2 measurements in the range of 56-65 mmHg.

Chronic obstructive pulmonary disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. Thorax 2004 Feb; 59 suppl 1:1-232.

The guideline notes that clinicians should be aware that inappropriate oxygen therapy in COPD patients may cause respiratory depression. LTOT is indicated based on current Medicare guidelines. LTOT must be administered for at least 15 hours per day and great benefits are seen with use 20 hours per day.

Global Initiative for Obstructive Lung Disease(GOLD),World Health Organization (WHO), NHLBI. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Bethesda (MD). 2004.

This guideline is an update to previous guidelines. Major points include a discussion regarding the lack of proven benefit for supplemental oxygen provided before, during, or after exercise and the ongoing consensus that administration of LTOT for patients with severe hypoxemia has been shown to increase survival.

6. Professional Society Position Statements

Adult domiciliary oxygen therapy. Position statement of the Thoracic Society of Australia and New Zealand. 2005.

The position paper notes that patients with COPD and stable daytime PaO_2 of $\leq$ 55 mmHg live longer and have a better quality of life if provided with LTOT.

7. Expert Opinion

Apart from the public comments discussed below, we have not currently received any expert opinions on the home use of oxygen for beneficiaries who do not meet the requirements of Section 240.2 of the CMS NCD Manual.

8. Public Comments

During the initial public comment period, CMS received written statements from three respiratory therapists, five associations, two physicians and six individuals (many of whom work in the health care field). These comments are available for review at http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca_id=169.

CMS received a total of 12 comments during the final 30 day public comment period. Six comments came from private individuals (including two physicians); one came from a hospital administrator, and five came from industry executives. None opposed the proposed decision to cover the use of oxygen in an NHLBI-sponsored clinical trial.

Comments about the evidence

Comment:

One industry executive commented that the studies he could find to review were flawed because overnight oximetry was not performed on a consistent basis to evaluate these patients. He believes that if LTOT response would have been measured in this matter, a greater reduction in mortality would be noticed and a larger response to the therapy would have been noted. He also commented that another variable not noted in the studies was "the improved kidney function that comes with LTOT for patients who have secondary kidney failure due to chronic hypoxemia."

Response:

CMS agrees that important questions still remain regarding the optimal use of LTOT. Specific research design elements and determination of appropriate outcomes will be undertaken after extensive consideration and in accordance with NHLBI's clinical trial protocol.

Comments about other aspects of the proposed decision memorandum

Comments:

One industry executive commented that the initial coverage policies included a paragraph for consideration of "other clinical indications" in addition to the testing data, and that as testing data qualifications were tightened, the original language supporting consideration of these other clinical indications was lost. He believes that there are certain patients who would benefit from supplemental oxygen in the home who have not yet demonstrated a PaO_2 below 59. He asks that other diagnostic and clinical data, e.g. spirometry, should be allowed for consideration for coverage for home oxygen in addition to the blood gas values.

A physician expressed support for CMS opening this topic, and made several suggestions. He asks that the patient's hemoglobin level should included in the criteria for coverage; that strict criteria for continued use be encouraged due to the "high cost and high profit margins" associated with this activity; that research needs to look at the person who "gets hooked" on oxygen even though the oxygen saturation measurements are "ok"; that criteria for oxygen saturation decrease during exercise should be established; and that criteria for standby oxygen be developed for patients whose condition acutely worsens due to cardiopulmonary events.

Response:

We do not believe at this time that there is sufficient evidence to support the use of spirometry or hemoglobin measurement in the place of arterial blood gas and oximetry measurements. Spirometry results are dependent on the voluntary effort of the person who is being tested. Hemoglobin measurements may be affected by many conditions, most of which are not appropriately primarily treated with long-term supplemental oxygen. CMS may reconsider this decision in the future if the results of future clinical trials demonstrate sufficient evidence to support a change.

Comments:

One commenter with a background in pulmonary rehabilitation noted that, in her experience, some patients with oxygen saturations of 89% at rest experience symptom improvement with supplemental oxygen.

One industry executive recounted the history of oxygen use and research on supplemental oxygen. He supported maintaining coverage for persons currently covered, and supported expansion of coverage in clinical trials for persons whose PaO_2 is up to 65 mmHg.

A hospital administrator commented that this is a worthwhile use of resources.

One individual noted that his own function improved significantly with supplemental oxygen, allowing him to be active in community affairs.

A physician strongly recommended expanding the coverage for home oxygen therapy to include those patients with the characteristics described in the proposed decision.

One commenter with a clinical background in respiratory care supported an expansion of coverage to the PaO_2 range of 55-65 mmHg, especially if the beneficiary has a diagnosis of lung cancer. He also commented that if CMS considers coverage up to 65 mmHg, (regardless of diagnosis, except lung cancer) then beneficiaries should be retested on a yearly basis.

Response:

CMS appreciates the time and effort taken by our multiple stakeholders, including beneficiaries, industry representatives and the medical community, to share their opinions and participate in the NCD process. The existing NCD provides for periodic recertification and retesting in beneficiaries meeting certain specified criteria. We would consider the applicability of this provision if appropriate for other beneficiaries receiving oxygen.

Comments:

An industry executive supported the possibility that new coverage criteria might be developed, and said that "this is a move that is very much needed."

One individual recounted the experience of a family member and supported looking for ways to expand the coverage criteria, requesting that the process from initial study to a standard happen quickly.

One commenter said that it was a great idea.

Response:

CMS appreciates the support expressed for this policy.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage.

Question:

Is the quality of evidence adequate to conclude that the home use of oxygen is reasonable and necessary for Medicare beneficiaries who have arterial oxygen partial pressure measurements from 56 mm Hg to 65 mm Hg or whose oxygen saturation is at or above 89%?

The evidence base for the use of home oxygen is strongest for the treatment of persons whose conditions are at the most severe end of the disease spectrum. Logical reasoning leads to a reasonable conclusion that supplemental oxygen is also beneficial for persons whose condition, while still seriously ill, has not yet progressed to the most severe end of the disease spectrum. CMS has previously determined that persuasive evidence exists of the health benefits of LTOT in persons who have a PaO2 $\leq$ 55 and for certain beneficiaries with a PaO2 from 56 -59. We have also recognized that, in certain circumstances, coverage for individuals with a PaO2 above 60 is reasonable and necessary. The evidence reviewed for persons who have a PaO2 between 55 and 65 is less persuasive but nonetheless encouraging since it builds upon a known benefit to a group that has a more severe form the same disease. However, the generalizability to the Medicare population at large of the conclusions drawn from the reviewed trials is limited by small sample sizes and the study protocols' focus on particular subsets of LTOT. We believe that important questions regarding the optimal daily use and long-term duration of LTOT for this subset of patients are not completely answered by the available data.

As we discussed in the Background section above, the use of supplemental oxygen is well established in medical practice and is not considered to be experimental. Supplemental oxygen has been associated with the risk of serious adverse events, but these can be adequately addressed with appropriate safeguards. Careful patient selection with pre-specified inclusion and exclusion criteria will minimize the likelihood of administering supplemental oxygen to a patient who has a higher risk of an adverse development. Stringent structured monitoring in a well designed and rigorously conducted clinical trial will facilitate prompt recognition of any remaining adverse developments that may develop in spite of careful patient selection. Such a clinical trial will assure informed individualized analysis and evaluation of the response to oxygen and patient health status, as well as an adequate plan for data and safety monitoring. We have carefully reviewed the NHLBI-sponsored clinical trial and have determined that it will provide this assurance.

The devices used to administer oxygen in these trials are the same devices that would be used absent a trial, and thus are neither experimental nor investigational. The oxygen itself is no different than the oxygen that is routinely administered to patients.

Our existing NCD 240.2.D.3(c) authorizes contractors to reimburse as reasonable and necessary oxygen for patients with PaO_2 levels at or above 60 or arterial blood oxygen saturation at or above 90 percent in some circumstances. We will instruct Medicare contractors that beneficiaries enrolled in these trials meet the current NCD standard under 240.2.D.3(c). The remaining provisions contained in sections 240.2 apply to all Medicare beneficiaries enrolled in one of these trials.

Thus, we believe the use of home oxygen in persons with a PaO_2 measurements between 55 and 65 Hg or whose oxygen saturation is at or above 89% who do not meet the current requirements for the home use of oxygen as detailed in Section 240.2.D.3 of the CMS NCD is reasonable and necessary when provided in a setting that has safeguards for patients to ensure appropriate patient evaluation and selection and reasonable use of home oxygen. Thus, we will provide coverage for the use of home oxygen in persons with a PaO_2 between 55 and 65 or whose oxygen saturation is at or above 89% in NHLBI-sponsored clinical trials. In light of the retesting provided by NHLBI-sponsored clinical trials, we would not separately apply the recertification and retesting provision described in Section 240.2.B during the period of their enrollment and participation to beneficiaries who are enrolled and participating in these trials.

Payment for home oxygen is the subject of this NCD. Payment for the other, routine clinical costs within the NHLBI-sponsored clinical trials covered under the Clinical Trial Policy (Section 310.1 of the National coverage determination manual).

IX. Conclusion

The Centers for Medicare & Medicaid Services (CMS) will cover the home use of oxygen as detailed in Section 240.2 of the CMS National Coverage Determinations Manual for beneficiaries who have arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% when they are enrolled in clinical trials approved by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI). The trials that are covered will be listed on the following CMS website: http://www.cms.hhs.gov/coverage.

This decision does not modify the existing requirement for coverage of oxygen currently identified in Section 240.2.

As a condition of coverage, investigators must adhere to the provisions of Health Insurance Portability and Accountability Act (HIPAA), the Privacy Act, Paperwork Reduction Act (PRA), and 45 CFR Part 46, if applicable.

We are adding the following text to Section 240.2.D.3(c) of the National Coverage Determinations Manual:

The home use of oxygen is covered for those beneficiaries with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI).

Appendices[PDF, 93KB]

---

[1] NHLBI Data Fact Sheet. Chronic Obstructive Pulmonary Disease. Publication No. 03-5229; March 2003.

[2] Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Nocturnal Oxygen Therapy Trial Group. Ann Intern Med 1980;93:391-8.

[3] Long term domiciliary oxygen therapy in chronic hypoxic cor pulmonale complicating chronic bronchitis and emphysema. Report of the Medical Research Council Working Party. Lancet 1981; 1(8222): 681-6.

[4] Lau J, Chew P, Wang C, White A. Long-Term Oxygen Therapy for Severe COPD. June 2004 Prepared for AHRQ by Tufts-New England Medical Center EPC.

[5] Croxton T, Bailey W. Long-term Oxygen Treatment in COPD. An NHLBI Workshop Report 2004.

Back to Top

Bibliography

Chaouat A, Weitzenblum E, Kessler R, Charpentier C, Ehrhart M, Schott R et al. A randomized trial of nocturnal oxygen therapy in chronic obstructive pulmonary disease patients. Eur Respir J 1999;14:1002-8.

Crockett AJ, Cranston JM, Moss JR, Alpers JH. Domiciliary oxygen for chronic obstructive pulmonary disease. The Cochrane Database of Systematic Reviews 2000, Issue 4. Art. No: CD001744.

Hjalmarsen A, Melbye H, Wilsgaard T, Holmboe JH, Opdahl R, Viitanen M. Prognosis for chronic obstructive pulmonary disease patients who receive long-term oxygen therapy. Int J Tubercul Lung Dis 199a; 3:1120-6.

Sandek K, Bratel T, Hellstron G, Lagerstrand L. Ventilation-perfusion inequality and carbon dioxide sensitivity in hypoxaemic chronic obstructive pulmonary disease and effects of 6 months of long term oxygen treatment. Clin Physiol 2001;21:584-93.

Sliwinski P, Hawrykiewicz I, Goreck D, Zielinski J. The acute effect of oxygen on pulmonary arterial pressure does not predict survival on long term oxygen therapy in patients with chronic obstructive pulmonary disease. Am Rev Respir Dis 1992;146:665-9.

Lau J, Chew P, Wang C, White A. Long-Term Oxygen Therapy for Severe COPD. June 2004 Prepared for AHRQ by Tufts- New England Medical Center EPC

Croxton T, Bailey W. Long-term Oxygen Treatment in COPD. An NHLBI Workshop Report. 2004

Crockett AJ, Cranston JM, Moss JR, and Alpers JH. A review of long-term oxygen therapy for chronic obstructive pulmonary disease. Respir Med. (2001) 95, 437-43.

Petty T, Casaburi R. Recommendations of the Fifth Oxygen Consensus Conference. 2000 Aug; 45 (8): 857-61

Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Nocturnal Oxygen Therapy Trial Group. Ann Intern Med 1980;93:391-8.

Long term domiciliary oxygen therapy in chronic hypoxic cor pulmonale complicating chronic bronchitis and emphysema. Report of the Medical Research Council Working Party. Lancet 1981; 1(8222): 681-6.

Snider G. Diagnosis of chronic obstructive pulmonary disease.www.uptodate.com; September 28, 2004

NHLBI Data Fact Sheet. Chronic Obstructive Pulmonary Disease. Publication No. 03-5229; March 2003.

Back to Top